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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/665,449 | 09/22/2003 | Alfred Weber | SCH-1743 C1 | 6844 |
| 23599 | 7590 | 10/24/2008 | EXAMINER | |
| MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201 | | | KAM, CHIH MIN | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1656 | |
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| | | | 10/24/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/665,449 | WEBER ET AL. | |
| | Examiner | Art Unit | |
| | CHIH-MIN KAM | 1656 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 03 July 2008.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 54-56,60-63,68-70,73,74 and 77-83 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 54-56,60-63,68-70,73,74 and 77-83 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 22 September 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. 09/509,608.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>7/3/08</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Status of the Claims

1. Claims 54-56, 60-63, 68-70, 73-74 and 77-83 are pending.

Applicants' amendment filed July 3, 2008 is acknowledged. Applicant's response has been fully considered. Claim 54 has been amended, and new claims 82-83 have been added. Therefore, claims 54-56, 60-63, 68-70, 73-74 and 77-83 are examined.

Maintained Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 54-56, 60-63, 68-70, 73-74 and 77-81 remain rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. New claims 82-83 are added to the rejection.

The instant claims are drawn to yeast strains and expression cassettes containing genes defined only by the enzyme they encode, wherein the enzyme is defined only by name, which name is indicative of a function. The instant claims are also drawn to methods of producing ergosterol or an intermediate product thereof using genes that are defined only by function.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a

precise definition, such as be structure, formula [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.” University of California v. Eli Lilly and Co., 1997 U.S. App. LEXIS 18221, at *23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

The instant specification describes the genes to be used in the claimed methods by virtue of function alone. No structures, other than specific species of genes (i.e., the genes in *S. cerevisiae* (yeast); page 2, paragraph 1) are described. No relation between the structure of the species (i.e., genes in altered form) and function is described. Thus, one of skill in the art would be required to predict new genes for use in the claimed methods based solely on their function, or the function of their encoded proteins. Such methods would not be predictably considering the minimal structural information provided in the specification. The lack of description on structure and function relationship for the genes encoding the enzymes, and lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

Response to Arguments

Applicants indicate the disclosure contained in the present specification (e.g., page 2, ¶1) explicitly teaches that the genes in *S. cerevisiae* (yeast) were known in field of microbiology prior to the filing date of the instant application (see the references provided in the IDS). The nucleic acid sequences of the genes recited herein were known and conventionally appreciated in the art before the filing date of the present application. Based on this information, a skilled artisan can readily determine both the nature (i.e., mutant or wild-type) as well as the structure (i.e., amino acid sequence) of the proteins encoded by the genes. As for the nucleotide sequence of t-HMG, ERG9, ERG1 and SAT1, ADH1 genes and/or the promoter sequences associated therewith, it is now well-settled that a specification need not disclose, and preferably omits, what is well known to those skilled in the art when an application is filed. Therefore, given the specification's disclosure of more than a representative number of species (for example, yeast species), further in view of the art knowledge of steroid biosynthetic pathway in yeast and humans, the skilled worker is fully in possession of written description of genes and the promoter sequences thereto. Regarding the standards set forth in *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997), since all that is required under *Lilly* is that the specification describes the molecule by "whatever characteristics sufficiently distinguish it." To a skilled worker, the recitation of the name of the genes provides a description of the structure (i.e., polynucleotide sequences, polypeptides encoded thereby) as well as functions of the gene products. As such, the present claims fully comply with the requirements under 35 USC § 112, ¶1. Therefore, the rejection should be withdrawn (pages 9-11 of the response).

Applicants' response has been fully considered, however, the arguments are not found persuasive because of the following reasons. While the genes in *S. cerevisiae* (yeast) were known in the art (see also page 2, ¶1 of the specification) prior to the filing date of the instant application, the claims, which are directed to suitable genes in altered forms, encompass altered genes of t-HMG, ERG9, ERG1 and SAT1 from various species. Although the specification and the art describe the wild-type genes of t-HMG, ERG9, ERG1 and SAT1 of *S. cerevisiae*, the altered t-HMG gene, and ADH1 promoter, neither the specification nor the art discloses various altered genes of t-HMG, ERG9, ERG1 and SAT1 from different species. Since there is no structure/function correlation for the altered genes of ERG9, ERG1 and SAT1, one of skill in the art could not predict the sequences of altered genes for use in the claimed methods based solely on their function, or the function of their encoded proteins. Thus, applicants have failed to sufficiently describe the claimed invention, and the rejection is maintained.

Conclusions

3. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/
Primary Examiner, Art Unit 1656

CMK
October 22, 2008